UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,747	03/27/2006	Judd Berman	IPT-075	4895

51414 7590 10/30/2009
GOODWIN PROCTER LLP
PATENT ADMINISTRATOR
53 STATE STREET
EXCHANGE PLACE
BOSTON, MA 02109-2881

EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
10/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentBos@goodwinprocter.com
hmcpeake@goodwinprocter.com
glenn.williams@goodwinprocter.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,747	BERMAN ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,13,14,17,24,25,31,34,50,51,53 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *34,53 and 54* is/are allowed.

6)☒ Claim(s) *1,2,5,13,14,24,25,31 and 49* is/are rejected.

7)☒ Claim(s) *6,17,50 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Current Status of 10/537747

1. In the instant application, claims 1, 2, 5, 6, 13, 14, 17, 24, 25, 31, 34, 49, 50, 51, and 53, and 54 are pending.

2. The rejections under 35 U.S.C. 112 2nd paragraph have been overcome by the amendment filed 18 June 2009.

3. The double patenting objections have been fixed by the amendment filed 18 June 2009.

Priority

4. In the instant application, priority for the entire genus of claim 1 goes back to 5 December 2003 (PCT/US03/38706). Priority for compounds in which variable A is a bicyclic group of 8-12 atoms, L is alkenyl, variable B is a bond, one instance of variable D is C, another instance of variable D is NR_1 has priority back to 60/465583, filed 25 April 2003. Priority for compounds in which variable A is bicyclic ring of 8-12 atoms or a tricyclic group of 12-16 atoms and L is alkyl, alkenyl, or cycloalkyl goes back to 60/431406, filed 6 December 2002. Provisional application 60/431406 provides support for instances of variables R_2 where variable B is C and variable D is C or N. The same provisional application provides support for an instance of variable R_2 where each instance of D is a different Carbon group (see pages 33 and 34 of 60/431406). All other compounds encompassed by instant formula I have priority back to 5 December 2003.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application

for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 24, 25, 31, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Adrianjara et al. (WO 2002064572, published 22 August 2002). Adrianjara teaches the following compounds: variable A is benzodioxole or 4-methoxy-phenyl; R_1 is H or Me, D is NR_1, where R_1 is H, methyl, benzyl, 4-carboxy-benzyl, 4-cyano-benzyl, 4-fluorobenzyl, or 4-CO_2Me-benzyl; D (next to variable B) is a C(O) group; and variable B is a bond. These compounds are recited in example 161 (page 146), 163 (page 147), 164 (page 149), 165 (page 151), 166 (page 151), step 2 product of example 164 (page 150), and step 3 product of example 164 (page 150). The last two compounds described are synthetic intermediates. Pharmaceutical compositions containing these compounds are described (page 32, line 12 through page 35, line 5). Intravenous administration is described from page 33, line 24 through page, line 7. Tablets and kits thereof are described (page 33, lines 20-23).

7. Claims 1, 2, 5, 24, 25, 31, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (WO 2001027103, published 19 April 2001). Miller teaches compound 4 (page 15). In compound 4, variable A is 1-methyl-indol-2-yl, NR_1 is NMe, L is C_2-alkenyl, NR_1 of R_2 is NH, D next to C(O) is NMe, and D next to B is CH_2, and B is a bond. Pharmaceutical compositions are described (page 18, line 10 to page 19, line 16). Liquid compositions (which include intravenous forms) are described (page 18, lines 16-19). Capsules are described (page 18, line 24 to page 19, line 2).

8. Claims 1, 2, 5, 13, 14, 24, 25, 31, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Berman et al. (US 20060142265, published 29 June 2006, claims priority to 60/455189, filed 17 March 2003). Berman teaches compound 4 (page 39). In this compound, variable A is 1-methyl-indol-2-yl, NR_1 is NMe, L is C=C, NR_1 of R_2 is NH, D next to C(O) of R_2 is NMe, D next to variable B is methylene, and B is a bond. Formulations are described (paragraphs 0620 through 0639, pages 50 through 52).

Intravenous formulations are specified in paragraph 0620, line 8. Capsules are described as well (page 0625, page 51).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. Claims 1, 24, 25, 31, and 49 are, are rejected under 35 U.S.C. 102(e) as being anticipated by Nahra et al. (WO 2004014869, published 19 February 2004, priority to 60/403520, filed 13 August 2002). Nahra teaches compounds 26, 27, and 28 (pages 152-153). In these compounds, variable A is 4-methoxy-phenyl, 3-pyridyl, or 5-pyrimidinyl, NR_1 is NH, NR_1 of R_2 is NMe, D (next to C(O) of R_2) is NR_1, wherein R_1 is CH_2-(4-(carboxy, SMe, or isopropyl)-phenyl, D (next to variable D is methylene, and B is a bond. Dosage forms are described (Page 171, line 3 to page 181, line 3). Intravenous forms are described (page 171, line 7) as well as tablet forms (page 171, lines 19-23).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sladowska et al. (*Farmaco, Edizione Scientifica*, **1986**, *41(12)*, 954-963).

Determining the scope and contents of the prior art

Sladowska teaches compounds XIX (page 956). In this compound, A is phenyl, NR_1 is NH, NR_1 of R_2 is N(benzyl), D (next to C(O) is NMe, D (next to B) is C(O), and B is a bond. The [2,3-*d*] ring is substituted with a methyl at its 2-position. These compounds is being used as anti-inflammatory, depressive, and analgesic compound (page 955, paragraph one).

Ascertaining the differences between the prior art and the claims at issue

In instant formula I, ring R_2 is unsubstituted on the pyridine portion. In compounds XI and XIX, the 2-position of the pyridine ring is substituted with a methyl group.

Resolving the level of ordinary skill in the pertinent art

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in preparation of compounds of the elected group.

Considering objective evidence present in the application indicating obviousness or nonobviousness

Sterling Drug Inc. v. Watson, Comr. Pats. (108 USPQ 37) teaches that the test to be applied in the matter of the patentability of a compound that is a homologue of another is that the beneficial characteristics are both unexpected and obvious."

In a comparison of the instant case and Sladowska, the only difference is the existence of a 2-methyl group instead of 2-H group. This compound is a final product in the paper, and it is mentioned that

these compounds have utility (although not in the same field). Based on the therapeutic potential of this compound (as described by Sladowska), it would be obvious to try compound XIX in the same method of use as the instant application.

Allowable Subject Matter

13. Claims 34, 53, and 54 appear free of the prior art of record.

14. Claims 6, 50, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Nahra (same reference as above) does not teach compounds where A is an oxygen-containing heterocyclic ring or compounds in which B is CH_2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624